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| 10/010,244 | 12/06/2001 | Robert Sixto JR. | SYN-064 A | 5798 |

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FELDMANGALE, P.A.
MIAMI CENTER, 19TH FLOOR
201 SOUTH BISCAYNE BOULEVARD
MIAMI, FL 33131

EXAMINER

PANTUCK, BRADFORD C

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,244

Applicant(s)

SIXTO ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 1, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 26, 27 and 29-33 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment #2</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 5, 6, 9-11, 27, and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,037,021 to Mills et al. Regarding Claims 1, 2, 5, and 6, Mills' method includes grasping the region of tissue from an interior surface of the stomach, and configuring the region of tissue to create at least one fold of tissue. As described in Column 6, lines 14-41, the clip (209) inserted by Mills' clip applier (200) manipulates the tissue (216) into a fold and holds the invaginated section after being inserted. The clip is locked in place [Column 6, lines 31-33] and will not let the stomach resume its pre-folded condition, because of the way that the staple *pierces* and encompasses the fold of tissue [see Figures 5a-5c].

The clip has two arms and a bridge coupling the two arms, as shown in Attachment #2. The clip (209) slides over the body tissue (216) when the body tissue is sucked into the chamber (and into the clip), as shown in Figure 5a, and described in Column 6, lines 20-22. As the tissue is sucked into the clip, it will *contact* Arm A [as shown in Fig. 5a], and presumably the clip and the tissue will *slide relative to each other*. As shown in Figure 5C, body tissue is located between the two arms. The clip applies a compressive force to the body tissue [Column 6, lines 30-34]. The clip

applier bends both of the arms, and one of them is bent through the whole thickness of the *both portions of tissue* [see progression from Figure 5a to 5c]. In Column 6, lines 22-28, Mills says that the remaining sections of the clip [i.e. Arm A and the bridge] are *deformed* (synonym for *bent*) during the application of the clip to the body tissue. Figure 5c shows Arm B being bent through the thickness of the body tissue. Thus both arms are bent during the application of the clip.

Mills discloses that his invention is intended to be used for “the attachment of materials or objects” to the *interior of the stomach* [Column 1, lines 44-45, 47-49].

2. Regarding Claim 9, Mills discloses compressing and clamping first and second portions of tissue (216) into contact with each other [see Fig. 5a] prior to sliding the clip and tissue sliding relative to each other. In Column 6, lines 9-10 Mills explains that prior to use the cavity is preloaded with the clip. Using logic, before the tissue can fit through the opening in the clipping device’s cavity (202) it must already be in a folded condition.
3. Regarding Claims 10, 11, and 30, the sliding and the bending are accomplished by using a single instrument. Column 6, lines 33-37 explain that the clip applier may contain a single clip or multiple clips. Further, only one [single] machine is used to carry out this process.
4. Regarding Claim 27, Mills discloses bending the piercing portion (in yellow – see Attachment #2) at acute angle Φ relative to the *longitudinal axis of the tissue from which the fold was made*. A portion of the piercing portion is also bent at an acute angle Θ relative to the *longitudinal axis of the fold* (Attachment #2).

5. Regarding Claim 29, the clip applies *some force* to the fold, in the configuration shown in Fig. 5a, previous to being bent and pierced through the tissue. For example the clip will apply at least the force of its weight (mass x gravity) on the fold. Said clip does not exert a *compressive force* on the fold before:

“subsequently bending the piercing portion of at least one of the two arms through the first portion of the fold and at least partially through the second portion of the fold.”

6. Regarding Claims 31 and 32, Mills discloses clip (209) being advanced over a “double layer of tissue” [Column 6, line 22] having two portions: with reference to Figure 5a, it is evident that the fold of tissue has a first “layer” (portion) on the right and a second “layer” (portion) on the left. The folded tissue defines a longitudinal direction, which is the same direction as the midline of the fold (up/down in Fig. 5a). The piercing portions of the clip are initially oriented (Fig. 5a shows the initial configuration) along (synonyms: next to, adjacent to, by) the midline of the fold.
7. Regarding Claim 33, Mills clip is advanced over two thicknesses of body tissue: the fold consists of two portions of tissue as is evident from Fig. 5a. Each portion of tissue has a thickness. The clip has been advanced over the body tissue in Fig. 5a, and the piercing portion (bottom arm) is shown being bent at elbow adjacent to member (205) in Fig. 5b. The piercing portion is further bent by the anvil in Fig. 5c.
8. Claims 1, 3, 4, 12, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,582,611 to Tsuruta et al. Regarding Claim 1, 3, 4, 26, and 33, the clip (22) has two arms and a bridge coupling the arms, as shown in

Figure 61. The arms are the parallel parts and the bridge is the perpendicular portion connecting the arms [see Figures 42 and 43]. Body tissue is located between the two arms, such that the clip applies force to the body tissue. *Each arm is bent through the entire thickness of the body tissue, such that the tips of the two arms contact each other* [see progression from Figure 42B to Figure 42C].

9. Regarding Claim 12, the clip connects two separate pieces of tissue. "Tissue a" is connected to "tissue b." There is a gap between the two tissues, therefore they are considered to be separate, i.e. disunited or withdrawn from each other [Fig. 42A; Column 18, lines 5-10].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,037,021 to Mills et al. in view of U.S. Patent No. 5,571,116 to Bolanos et al.

10. Regarding Claim 7, Mills discloses manipulating the region of tissue to create at least two adjacent folds of tissue [Column 6, lines 30-38]. Assumedly, one embodiment of Mills' device contains at least two staples so that they can be applied to folds of tissue close to the location of the first clip.

11. Regarding Claim 8, Mills discloses grabbing the interior of the stomach with a grasping instrument and pulling on the interior of the stomach to cause invagination of the interior of the stomach. Using suction, the tissue is *pulled* into the cavity (202) in the clip applier [Column 6, lines 7-9; Fig. 5a]. During the clipping process, the interior of the stomach is held in the cavity of the grasping instrument *both by the vacuum and by the incidental contact between the tissue and the grasping instrument*. Further, Mills discloses holding the tissue mechanically [grabbing it], with piston 205 [see Fig. 1b].

With regards to Claims 7 and 8, Mills does not disclose that his procedure is done specifically in the part of the stomach called the *fundus*. However, Bolanos teaches that one would bend clips having two arms and a bridge completely through a fold of the fundus in the stomach *in order to help alleviate gastroesophageal reflux disease*. Mills teaches that in order to treat this disease effectively, one ought to attach the patient's lower esophagus to the patient's fundus [Column 2, lines 55-62]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to perform the surgery disclosed by Mills to attach the lower esophagus to the fundus in order to alleviate gastroesophageal reflux disease in a patient, as taught by Bolanos.

Allowable Subject Matter

12. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Response to Arguments

14. Applicant's arguments filed March 1, 2005 have been fully considered but they are not persuasive. Applicant argues in "Remarks/Arguments" (on page 3 last paragraph) that the clip found in the applied prior art reference U.S. Patent No. 5,037,021 to Mills et al. has only one piercing portion. Examiner disagrees, and has thoroughly explained his position regarding this issue in item 13 of the Non-Final Rejection mailed November 1, 2004. Examiner has already explained that as with any staple, Mills' staple has two arms with a *tip* at the end of each [Column 6, line

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26]. Admittedly, only one of the tips is *shown* piercing tissue, but *both tips are capable of piercing tissue* and *would pierce tissue* if the tip were pushed into tissue.

Examiner maintains that the both tips of a staple are rightfully called piercing portions, even if only one of the tips actually pierces something. Analogously, if a cleric used his stapler sitting on his desk to staple a piece of paper, but only drove one of the staple tips through the paper (the other tip is driven into the anvil, but just misses the edge of the page) would the cleric not rightfully call both tips “piercing portions?” As a second analogy, if while at the beach one stepped on a sea urchin, would the needles that did not pierce the bather’s foot also be properly called “piercing portions?” As a third analogy, while someone uses a toothpick to pick her teeth after eating, she accidentally pierces her gums, causing bleeding in her mouth. Would the person not accurately refer to either (identical) end of the toothpick as a “piercing portion,” since the ends are identical, and either end would have pierced the tissue?

15. Regarding Applicant’s concern about not receiving Attachment #2 with the Office Action mailed on November 1, 2004, Examiner notes that Applicant called the USPTO to point out the error and Examiner faxed this missing document as requested, in a timely fashion. Since the Attachment #2 meant to be included with the office action of November 1, 2004 is substantially the same as Attachment #2 in the April 15, 2004 Office Action, Examiner maintains that no extension of time is necessary.

16. Regarding Applicant's arguments about the limitation "initially orientated along the longitudinal direction" [see Remarks/Arguments pages 5-6], Examiner maintains that Mills '021 meets this limitation. The word "along" interpreted in its broadest reasonable sense can mean "next to" or "adjacent to" or "close to" or "by." Mills' staple is shown in its initial configuration in Fig. 5a and both piercing portions are shown located close to/adjacent to the longitudinal axis of the tissue fold. However, with regards to claim 32, the piercing portions of Mills' clip cannot be considered to be orientated *parallel to* the longitudinal direction.
17. Applicant's arguments on pages 10 and 11 of "Remarks/Arguments", filed March 1, 2005, with respect to claim 33 have been fully considered and are persuasive. The rejection of claim 33 with U.S. Patent No. 5,582,611 has been withdrawn, *however the rejection of claim 33 with U.S. Patent No. 5,037,021 to Mills still remains.*
18. On pages 12 and 13, Applicant argues that U.S. Patent No. 5,571,116 to Bolanos does not disclose advancing a clip over body tissue. Regarding being "over" tissue, it is perfectly clear that the clip is *over the tissue*: that is the clip is located *on top of* or *above* the tissue while it is being advanced [see Fig. 6B]. Thus, the clip is advanced over tissue. In another sense the clip is advanced over/through tissue, while the arms of the clip are being driven through the tissue [also see Fig. 6B].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
April 7, 2005


GLENN K. DAWSON
PRIMARY EXAMINER

U.S. Patent

Aug. 6, 1991

Sheet 5 of 8

5,037,021

Longitudinal
Direction
of Fold.

ARMA

Arm B
w/ (piercing portion)

piercing portion
bent at
angle θ

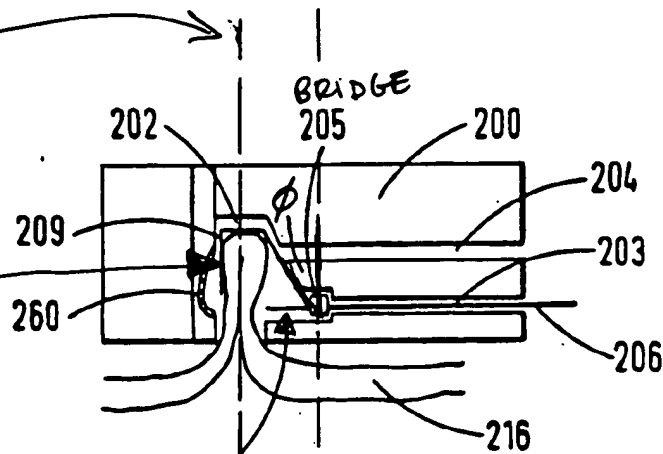


Fig. 5a

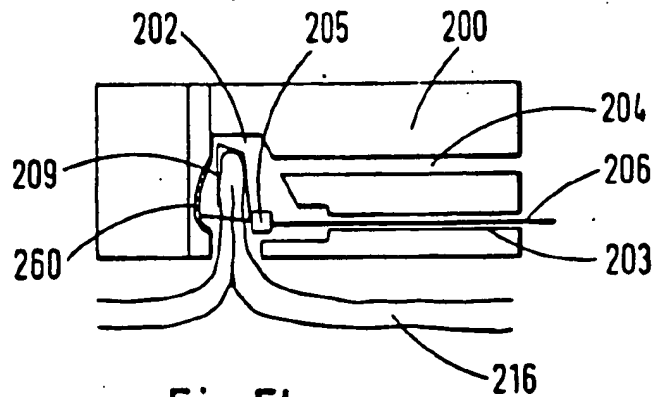


Fig. 5b

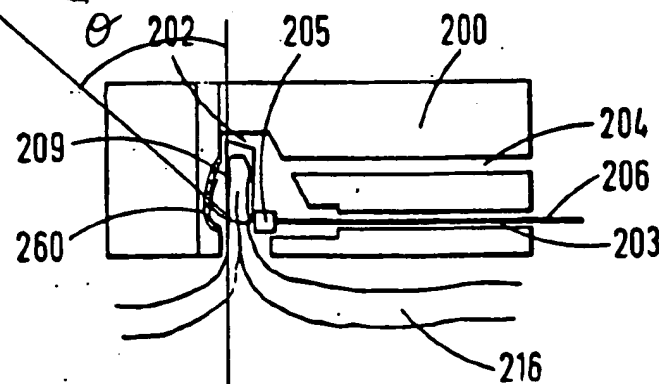


Fig. 5c